UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,433	05/10/2002	Bastian Nuyen	4512 00004	4574

26161 7590 06/29/2005

FISH & RICHARDSON PC
225 FRANKLIN ST
BOSTON, MA 02110

EXAMINER	
WINSTON, RANDALL O	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/622,433	NUYEN ET AL.	
	Examiner	Art Unit	
	Randall Winston	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 12-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 12-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0101,0505,1004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of the receipt and entry of applicant's response to the election/restriction requirement on 04/06/2005.

Examiner has acknowledged that claims 9-11 have been withdrawn for consideration.

Claims 1-8 and 12-25 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 12-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase "a lyophilized didemnin preparation including water soluble material and a reconstitution solution of mixed solvents" The above phrase is unclear because it appears to examiner that applicant's claimed lyophilized didemnin preparation includes both a water-soluble material and a reconstitution solution of mixed solvents. The above phrase seems to be inconsistent to what is claimed in claim 8 and claim 20 whereas the lyophilized didemnin preparation appears to be separate from the reconstitution solution. Correction is required.

Claim 3 is rendered vague and indefinite for the phrase "the didemnin is chosen." The above phrase should be more consistent with claim 15. For example, the above phrase should be rewritten in MarKus Group form. Correction is required.

Claim 8 is rendered vague and indefinite by the term "including." The metes and bounds of the above term cannot be delinated. It is suggested that applicant replace the term "including" with language such as "comprising" or "comprised" of etc. Correction is required.

Claim 21 and 22 recite the limitation of "the alkanol/water mix." There is insufficient antecedent basis for the limitation in the claim because the limitation is not recited in Claim 1.

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 and 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Crumb et al (US 6,030,943).

As being very unclear as drafted, applicant apparently claims a kit comprising firstly of a lyophilized didemnin preparation comprised of a didemnin and a water-soluble material and secondly of a reconstitution solution comprised of mixed solvents.

Crumb et al. anticipate the claimed invention (i.e. column 5 lines 50-67 and column 6 lines 1-21, see especially lines 16-21 of column 6) because Crumb et al. teach a pharmaceutical composition may be in form of a container (i.e. the kit is a container) comprising firstly of a lyophilized didemnin preparation comprised of a didemnin (i.e. aplidine) and a water soluble material (i.e. mannitol) and secondly a reconstitution solution comprised of carriers such as mixed solvents (i.e. water and surfactants). (please note that it is acknowledged by examiner that the purpose a reconstitution solution is to aid in the administration of pharmaceutical's active ingredients to a subject whereas the reference teaches reconstitution with solvents, see e.g., column 6 lines 16-21). Therefore, the reference is deemed to anticipate the claimed invention.

{Please note, the intended use of the above claimed composition (i.e. claim 2) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112). }

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 12-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crumb et al. in view of Gyory et al. (US 5,883,135)

As being very unclear as drafted, applicant apparently claims a pharmaceutical composition and a kit comprising firstly of a vial of a lyophilized didemnin preparation comprised of a didemnin, a water-soluble material and an alkanol/water mixture and secondly of a vial of a reconstitution solution comprised of mixed solvents such as a nonionic surfactant/alkanol/water mixture for the administration to a subject.

Crumb et al. teach a pharmaceutical composition may be in form of a container (i.e. a kit is a container) comprising firstly of a lyophilized didemnin preparation comprised of a didemnin (i.e. aplidine) and a water soluble material (i.e. mannitol) and water secondly a reconstitution solution comprised of carriers such as mixed solvents (i.e. water and surfactants) for the purpose of aiding in the administration of the pharmaceutical to a subject. Crumb et al. do not expressly teach that the claimed active ingredient of an alkanol should be contained within the pharmaceutical composition and Crumb et al. do not expressly teach the claimed active ingredients' ranges.

Gyory et al. benefically teach (see, e.g. column 3 line 5-10 and also in other publication page 1 see Ferber, et. al.) that the claimed active ingredient of alkanol is an

effective carrier and/or effective delivery enhancer to aid in the administration of an active ingredient to a subject.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Crumb et al.'s pharmaceutical composition and/or kit to include Gyory et al.' alkanol active ingredient within Crumb's pharmaceutical composition and/or kit because the two combined teachings would create an improved claimed pharmaceutical composition and/or kit for enhance delivery of the pharmaceutical composition's active ingredients to a subject. Furthermore, the adjustment of other conventional working conditions (e.g. the substitution of one functional equivalent alkanol for another, the ranges of each active ingredient and the substitution of one surfactant for the other), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

{Please note that the patentability of a product (i.e. claim 20) does not depend upon the method of production. If the product in a product by process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process. (see, e.g. MPEP 2113).}

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER R. TATE
PRIMARY EXAMINER